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the group consisting of SEQ ID. No: 1, SEQ ID NO. 2 and their complementary sequences.

- 29. A fragment of a nucleic acid specific to mycobacteria of M. tuberculosis complex having a nucleotide sequence selected from the group consisting of SEQ ID No: 1 and its complementary sequence.
- 30. A fragment of a nucleic acid specific to mycobacteria of M. tuberculosis complex which fragment is different from BCG, and has a nucleotide sequence selected from the group consisting of SEQ ID No: 2 and its complementary sequence.
- 31. A cloning or expression vector containing a nucleic acid sequence of claim 28.
- 32. A vector of claim 31 which is a plasmid selected from the group consisting of pRegX3Bcl and pRegX3Mtl deposited at CNCM under Nos. I-1765 and I-1766, respectively.
- 33. A nucleotide probe or nucleotide primer that hybridizes under high stringency conditions with one of the sequences of claim 28, its corresponding RNA sequences or its corresponding gene, and that contains a maximum of 21 base pairs.
- 34. A nucleotide probe of claim 33 comprising 24 consecutive nucleotides selected from the sequences of claim 28.
- 35. A nucleotide probe of claim 33 comprising sequence SEQ ID No: 1 or its complementary strand.
- 36. A nucleotide probe of claim 33 comprising two successive sequences SEQ ID NO: 1 followed by a sequence SEQ ID No: 2.
  - 37. A nucleotide probe for detection of specific sequences of

nucleic acids of M. tuberculosis complex other than BCG comprising a sequence of the region of sequence SEQ ID No: 2 comprising the GAG codon in positions 40 to 42 or its complementary strand.

- 38. A nucleotide probe of claim 37 comprising a sequence composed of 9 base paris upstream and 9 base paris downstream of the GAG codon in positions 40 to 42 or its complementary strand.
- 39. A nucleotide probe of claim 37 comprising a sequence composed of 9 base paris upstream and 9 base paris downstream of the GAG codon in positions 40 to 42.
- 40. A nucleotide probe of claim 37 comprising the sequence SEQ. ID No: 2 or its complementary strand.
  - 41. A nucleotide probe of claim 33 labelled by dioxygenin.
- 42. A nucleotide primer pair for amplification of a specific nucleotide sequence of mycobacteria of M. tuberculosis complex, said pair comprising the nucleotide sequence of sequences adjacent to the senX3-regX3 region in the 3' of seX3 and 5' of regX3 regions.
- 43. A nucleotide primer of claim 42 comprising 19 nucleotides.

primers 5'GCGCGAGAGCCCGAACTGC3' AND 5'GCGCAGCAGAAACGTCAGC3'.

- 45. In an enzymatic amplification method, the improvement comprising using as the diagnostic probe or primer a fragment of claim 28.
- 46. In the detection or diagnosis of a strain belonging to M. tuberculosis complex, the improvement comprising as the <u>in vitro</u>



tool, a nucleotide probe or nucleotide primer of claim 33.

- 47. A method of detecting a mycobacteria stain of M. tuberculosis complex in a biological sample comprising (1) contacting the biological sample to a pair of primers of claim 42 under conditions to effect hybridization of the primers to the specific nucleic acids of mycobacteria strains of M. tuberculosis complex, (2) effecting amplification of the said nucleic acids, (3) contacting the biological sample with a nucleotide probe of claim 33 under conditions for formation of hybridization complexes between the said probe and amplified sequences of nucleic acids and (4) detecting if any hybridization complexes are present, which complexes indicate the presence of a mycobacteria strain of M. tuberculosis.
- 48. The method of claim 47 wherein the nucleotide probe is that of claim 35.
- 49. The method of claim 47 wherein the nucleotide probe is that of claim 37.
- 50. The method of claim 49 effected upon immunodeficient humans to differentiate an infection by BCG from an infection by a virulent mycobacterium of M. tuberculosis complex.
- 51. The method of claim 50 wherein the human is infected with HIV.
- 52. A method of identifying groups of mycobacteria belonging to a M. tuberculosis complex comprising (1) contacting the DNA of previously extracted strains of the M. tuberculosis complex with a pair of primers of claims 35 and 42 under conditions permitting a



 specific hybridization of the primers with one of the sequences of claim 28 to obtain amplification products and (2) measuring the length of the amplification products obtained.

5. The method of claim 52 wherein the pair of primers are 5. GCGCGAGAGCCCGAACTGC3. AND 5. GCGCAGCAGAAACGTCAGC3.

- 54. A kit for in vitro identification of strains of mycobacterial of the M. tuberculosis complex in a biological sample comprising (1) a primer pair for amplification of a specific nucleotide sequence of mycobacteria of M. tuberculosis complex, said pair comprising the nucleotide sequence of sequences adjacent to the senx3-regx3 region in the 3' of sex3 and 5' of regx3 regions.
- 55. A method of detection and of differential diagnosis of BCG and the members of M. tuberculosis complex in a biological complex comprising:
- (1) contacting the biological sample to a nucleotide primer pair for amplification of a specific nucleotide sequence of mycobacteria of M. tuberculosis complex, said pair comprising the nucleotide sequence of sequences adjacent to the senX3-regXe region in the 3' of seX3 and 5' or regX3 regions under conditions to effect hybridization of the primers to the specific nucleic acids of mycobacteria strains of M. tuberculosis complex;
  - (2) effecting amplification of the said nucleic acids;
- (3) contacting the biological sample with a nucleotide probe of two successive sequences SEQ ID No: 1 followed by a sequence SEQ ID NO: 2 under conditions for formation of hybridization complexes